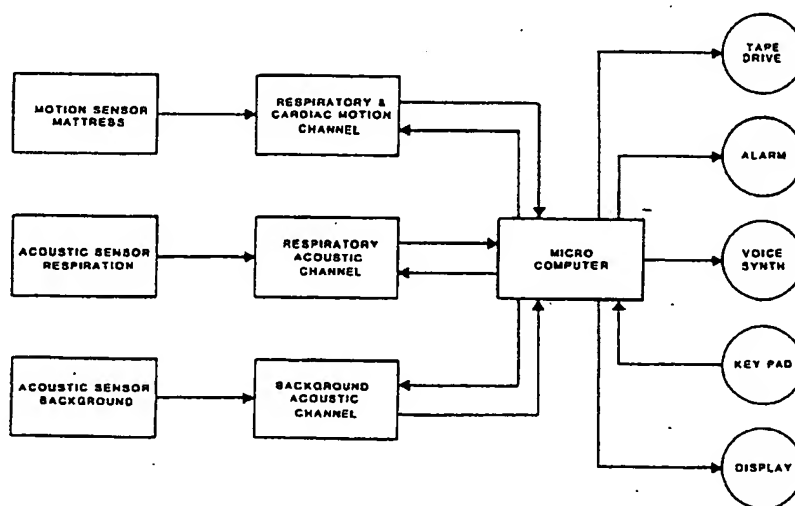




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(54) Title: MULTI-CHANNEL VENTILATION MONITOR AND METHOD



(57) Abstract

The ventilation monitor includes one or more discrete sensors and a plurality of independent channels for processing the input signals from each of the discrete sensors. The principle category of sensor used in conjunction with this ventilation monitor is capable of the reception of information associated with breathing and cardiovascular movement. A second category of the sensor which can be used in conjunction with this ventilation monitor is capable of the reception of audible sounds associated with breathing. Each of the individual input signals from these sensors is initially verified as being indicative of the sensation being monitored and, thereafter, compared in real time with one another and criteria stored within a microprocessor. The purpose of the comparison is to verify a normal breathing pattern and signal an alarm when the breathing pattern is abnormal. The ventilation monitor is also provided with means to dynamically adjust the gain and frequency response of each channel to accommodate changes in the monitored subject's position and physiological states.

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TITLE: MULTI-CHANNEL VENTILATION MONITOR AND METHOD**CROSS-REFERENCE TO RELATED APPLICATION**

5 This application is a continuation-in-part of copending application serial number 753,069, filed on April 10, 1985.

BACKGROUND OF THE INVENTION

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Field of the Invention - This invention is directed to an apparatus and to a method. More specifically, this invention concerns a multi-channel ventilation monitor and a method for real time monitoring of multiple signals associated with breathing and cardiovascular activity.

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Description of the Prior Art - The monitoring of physiological activity of individuals with various types of instrumentation is an accepted method used by clinicians to detect abnormalities in biological functions. Monitors are available to measure cardiovascular activity, respiratory activity, and central nervous system activity. In the monitoring of physiological activity, a sensor is generally affixed to the individual and, in turn, connected to a signal interpreter. The signal interpreter can be relatively simple (i.e. U.S. Patent 4,169,462 - to Strube), or involve relatively simple and unsophisticated information processing (i.e. U.S. Patents 4,306,567 - to Krasner; and 4,356,825 - to Veth).

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In the device described by Strube, an electromechanical transducer, incorporating a piezoelectric crystal, is attached to the monitored subject. The transducer is used

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to detect variation in mechanical pressure resulting from breathing activity. Upon detection of such motion, the transducer relays an impulse, in the form of an electrical signal, to a counting circuit. An oscillator is associated with the counting circuit which in turn is preset to a predetermined counting period. The oscillator simply feeds a repetitive signal into the counter. If the transducer fails to generate a signal within a predetermined counting period to reset the counter, a switch is closed by the counting circuit which in turn triggers the alarm.

In the device described by Krasner, a sensor is attached to the monitored subject which is sensitive to acoustical signals indicative of a physiological rhythmic function. The Krasner device is designed to monitor acoustical signals within a relatively narrow frequency. These signals result from mechanical displacement of the body beneath the sensor. The design of the sensor and its attachment directly to the skin of the subject, is reputed to reduce the amount of spurious and environmental noise, in an attempt at enhancement of the signal-to-noise ratio. The electrical signal from the sensor is demodulated to enable detection of the periodic amplitude and modulated frequencies of the electrical signal. Once the signal has been reshaped or standardized, it is further processed to eliminate artifact within the predetermined acoustical frequency of interest. This further processing involves comparison of the duration of the demodulated signal, within the frequency bandwidth of interest, to a function rate signal. The Krasner monitor is designed to reject any signal within the frequency bandwidth of interest if it is less than or in excess of a predetermined signal duration (signals of less than 400 milliseconds duration and longer than 3-4 seconds being rejected as attributable

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to artifact). The relatively simplistic information processing logic of Krasner is thus unable to discriminate between true artifact and respiratory signals which may be outside the system parameters.

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In the device described by Veth, a series of sensors are attached to the monitored patient for detection of different physiological activities (i.e. pulse rate, respiration and temperature). The data collected from these sensors is interpreted by a digital microprocessor associated with this electrical measuring system. This device is capable of intermittent measurement and processing of the input signal from only a single activity at any one time. The input signal is compared to a system clock, which utilizes a conventional oscillator (with an adjustable output frequency) as a standard. As is evident from the emphasis by Veth on rapid data analysis, his device is directed to an intermittent data sampling system. More specifically, the detection of successive data points is based upon a data sampling scheme involving the collection of a limited number of samples; the sampling interval and count frequency being controlled by a voltage controlled oscillator output signal. Accordingly, the Veth device is designed to restrict data sampling to a relatively brief period; with the data points being selected in this preselected interval and the interval being controlled by the voltage control oscillator.

30 The devices described hereinabove are fairly typical of those presently commercially available. Each of the above devices described by Krasner and Veth, respectively, share certain basic information processing similarities, (i.e. root mean square processing of signal data) as well as
35 lack the ability to discriminate between apnea which is

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associated with obstruction of the breathing passageway from apnea which originates within the central nervous system (CNS). In addition, each of the foregoing devices lacks the ability to "effectively" distinguish between
5 normal respiration and respiratory activity which may be indicative of an apnea episode. The reason for this deficiency is the inability of these systems to dynamically accommodate, or adjust, themselves to changes in the body position or the level of respiratory activity
10 of the monitored subject. Thus, when the monitored subject is awake at the time monitoring commences, or is sleeping and progressively goes into a deeper sleep state, the level of physiological activity of the patient will change and the relative frequency of the signal will also
15 change accordingly. When the sensitivity of the instrument is set to accommodate the initial activity state, it cannot effectively monitor the patient as the activity state becomes progressively more shallow. Attempts at overcoming this deficiency by setting the
20 initial sensitivity at a very high level results in frequent false alarms and, thus, tends to impair the credibility of the monitor. The individual responsible for responding to such an alarm may not react quickly enough to intervene in a real emergency because of the
25 skepticism which is created due to numerous false alarms. Conversely, where the sensitivity is set to accommodate the initial activity state, the monitor will be unable to effectively identify a true apnea episode requiring intervention as the physiological activity level becomes
30 more shallow. Thus, there is a continuing need for improvement in respiration and ventilator monitors to reduce or eliminate the frequency of false alarms and yet provide effective monitoring of the patient at various and ever changing levels of respiratory activity.

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OBJECTS OF THIS INVENTION

It is the object of this invention to remedy the above as well as related deficiencies in the prior art.

5 More specically, it is the principle object of this invention to provide a multi-channel ventilation monitor that is sensitive to distinct physiological activities indicative of respiration.

10 It is another object of this invention to provide a multi-channel ventilation monitor capable of real time monitoring of multiple signals indicative of respiration.

15 It is yet another object of this invention to provide a multi-channel ventilation monitor in which the sensors are not intimately attached to the monitored subject, nor incorporated into a garment or a harness that must be worn by the monitored subject.

20 It is still another object of this invention to provide a multi-channel ventilation monitor capable of real time monitoring of movement and sound indicative of respiratory activity.

25 It is an additional object of this invention to provide a multi-channel ventilation monitor capable of dynamic adjustment of gain and frequency response for each of the sensed physiological activities to accommodate changes in
30 the levels of each such activity.

It is yet an additional object of this invention to provide a multi-channel ventilation monitor which can identify an obstructive apnea episode.

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5 It is still yet an additional object of this invention to provide a multi-channel ventilation monitor which can distinguish between obstructive apnea and an apnea episode which originates within the central nervous system (CNS).

10 It is a further object of this invention to provide a multi-channel ventilation monitor which incorporates both a base station and a portable unit, each of which can share data with the other which is accumulated as a result of independent monitoring the patient with either unit.

15 Further additional objects of this invention include the provision of an improved method for monitoring multiple physiological activities indicative of respiration.

SUMMARY OF THE INVENTION

20 The above and related objects are achieved by providing a multi-channel ventilation monitor for real-time monitoring of multiple physiological activities associated with breathing and cardiovascular activity. This ventilation monitor is provided with one or more distinct types of sensors for monitoring physiological activity associated with breathing motion and cardiovascular motion. In one of the preferred embodiments of this invention, a discreet sensor is provided to monitor the audible sounds associated with breathing activity. Each of the channels, which is responsible for processing the signal associated with each of these sensations, is independent of the other (i.e. motion signal processing being monitored on a channel which is separate and distinct from the channel dedicated to monitoring of audible information). This ventilation monitor is further unique in that the preferred system components need not be in intimate

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contact with the patient, (ie. no requirement that the sensor be incorporated within a harness or that an electrode be attached to the patient) and yet can still accommodate patient movement without loss or disruption of the ventilation monitoring function. This preferred system can thus be characterized as an "ambient" monitor; that is the monitoring of the patient is achieved by detection of physiological activity in the immediate environment of the patient.

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In another of the preferred embodiments of this invention, the system includes the capability to dynamically adjust the sensitivity of the monitor to accommodate different levels of activity, (i.e. distinct sleep states) of the patient. This is achieved by real time comparison of the sensed input over a relatively brief interval, identifying a trend in the sensation which is being monitored and automatically adjusting the gain and frequency response to conform to this sensed trend. By continuously monitoring and adjusting the gain and frequency response to changes in the monitored sensation, as necessary, the sensitivity of the ventilation monitor can be maintained at its highest level while avoiding the occurrence of false alarms.

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In another of the preferred embodiments of this invention, the system includes a piezoelectric transducer within a mattress which is used to detect physical movement associated with breathing activity and movement associated with cardiovascular activity (hereinafter referred to as "ballistic cardiogram" or "BCG"). The input signal from this single transducer is monitored for distinct signal frequencies characteristic of each such activity. This monitoring of both of these physical activities can be achieved without attachment of the piezoelectric

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transducer to the patient and is also independent of patient orientation and movement relative to the transducer.

5 In another of the preferred embodiments of this invention, the audible sounds associated with breathing are detected with either a directional microphone or with an array of microphones. The monitoring of audible sounds associated with breathing activity permits discrimination between
10 obstructive apnea and CNS apnea. The microphone array is preferred because of its ability to differentiate background noise (i.e. sounds associated with the ambient environment) from sounds indicative of breathing activity.

15 In yet another of the preferred embodiments of this invention, the monitor consists of two separate units which are integral with one another and yet each capable of independent operation. For ease of differentiation, one unit is referred to as the "main or base station" and
20 the second unit is referred to as the "module or portable unit". This portable unit is "docked" within the base station. In practice, the patient (typically an infant) is monitored in its crib at home or in the hospital utilizing the main station. The data acquired during this
25 monitoring activity is shared with the portable unit which can then be used to continue such monitoring away from the home or hospital environment. The data acquired by the portable unit is retained by it and later shared with the main station when the two monitors are reunited.

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BRIEF DESCRIPTION OF THE DRAWINGS

Figs 1(a) to (d) are a series of diagrams illustrating the relationship of the various components of the

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multi-channel ventilation monitor of this invention which is equipped with both motion and accoustical sensors.

5 Fig 2 is a flow diagram illustrating the signal processing logic of the multi-channel ventilation monitor of this invention.

10 Fig. 3A is an expanded illustration of the cardiovascular signal processing logic of Fig 2.

Fig 3B is a continuation of the cardiovascular signal processing logic from point B of Fig 3A.

15 Fig 4A is an expanded illustration of the mattress signal processing logic of Fig 2.

Fig 4B is a continuation of the mattress signal processing logic from point B of Fig 4A.

20 Fig 5 is an expanded illustration of the audio-respiratory signal processing logic of Fig 2.

25 Fig 6 is an expanded illustration of the signal processing logic for the alarm date circuit of Fig 2.

Fig 7 is an expanded illustration of the signal processing logic for the gain check adjustment of Fig 2.

30 Fig 8 is a perspective view of an embodiment of the monitor of this invention which incorporates a base station and a portable unit in docking relation to one another.

35 DESCRIPTION OF THE INVENTION
INCLUDING PREFERRED EMBODIMENTS

- 10 -

The ventilation monitor of this invention can be configured with one or more sensors to monitor motion (patient movement associated with breathing and cardiovascular activity); and, preferably, with additional
5 sensors capable of detection of discernible physiological phenomena indicative of a function complimentary to or independent of breathing activity

Fig 1 (a) to (d) are a series block diagrams depicting the
10 overall interrelationship of the components of one of the preferred multi-channel ventilation monitors of this invention. As is evident from these diagrams, the device illustrated in Fig 1 (a) has only three (3) channels; however, this diagram is only illustrative and is not to
15 be construed as indicative of limits of this system, or of the signal processing capabilities of this invention. For example, additional channels can be added to the system to process signals from a temperature sensor and/or from a transcutaneous sensor for PO_2 or PCO_2 .

20 As more fully illustrated in Figs. 1(b) - (d), input signals from a series of sensors generate distinctive electrical signals which are amplified, filtered, converted from analog to digital information and
25 thereafter manipulated by a microprocessor. One of the unique aspects of this invention is the ability of the microprocessor to dynamically adjust the gain of the variable amplifiers in response to changes in the level of the monitored activity. More specifically, where an
30 infant is monitored continuously, the body position and monitored level of physiological activity, (i.e. distinct sleep states) will change and the relative level of sensitivity of the monitor must be adjusted accordingly. In the signal processing channel illustrated in Fig. 1(b),
35 such adjustment occurs automatically. Similarly, dynamic

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adjustment of the low pass and band-pass filters is also performed automatically in response to changes in activity levels. Both the variable gain amplifier and the adjustable low-pass and band-pass filters are under
5 microprocessor control and such adjustment is made in response to information received and stored in the microprocessor.

The monitor of Fig. 1(a) utilizes both a motion sensor and
10 two (2) acoustical sensors. The motion sensor can function independent of the acoustical sensor or in combination with other sensors. The motion sensor of Fig. 1(b) of this device is preferably incorporated within the mattress. Movement by the subject laying upon the
15 mattress will result in generation of electrical signals by a transducer within the mattress, (i.e. piezoelectric film of polyvinylidene fluoride). The electrical signals which are of interest include the patient's movements associated with respiration and subtle patient movements
20 associated with cardiovascular activity. The electrical signal from this transducer is amplified by a differential amplifier and the signal frequency band associated with respiration and signal frequency band associated with cardiovascular motion are processed independently of each
25 other through separate band pass filters which are under microprocessor control. The analog input voltage from each channel is then driven by a buffer to an analog multiplexer, where the analog input voltages from each signal is sampled in turn, converted into digital
30 quantities by the analog to digital converter and communicated to the microprocessor. The response and control of the microprocessor over this information will be discussed in detail in review to the microprocessor system logic. The communication of this information to
35 the microprocessor enables dynamic system control over

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both the variable gain amplifier and adjustable band pass filters.

5 The two other channels illustrated in Figs. 1(c) - (d) are designed to process an input signal from acoustical sensors. Both channels are virtually the same, except for the frequency which each monitors; one channel being dedicated to processing of an acoustical signal at a frequency band indicative of breathing activity (for the
10 detection of "obstructive APNEA"), and the other channel being dedicated to the processing of an acoustical signal at a frequency band indicative of background (off-center impulsive noise). The acoustical signal is initially passed through a parametric amplifier for low noise
15 amplification, the signal voltage adjusted by variation in the amplifier gain, filtered and the analog voltage converted to digital quantities. The digital signal is further filtered through a digital signal processor. The digital signal processor contains a speech recognition
20 chip. The combined output from these components is the derivation of a set of linear predictive coding coefficients (LPCs) which are analyzed by the main processor for breathing pattern recognition.

25 As will become evident from the discussion of the system processing logic, the programed microprocesor of the monitor provides a degree of control over physiological signal data processing not heretofore available. The microprocessor functions include: (1) continuous
30 monitoring of the input signals from each of these sensors; (2) continuous updating of its own data base on the monitored individual to detect trends in the physiological activities; (3) dynamic adjustment of the gain of the variable gain amplifier to accommodate changes
35 in the level of physiological activity and dynamic

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adjustment of the various filters (band pass and low pass filters) to compensate for changes in signal frequency content incidental to such activity level variations; (4) analyzing the wave form of the input signal for characteristic shapes associated with abnormal breathing activity; (5) continuous monitoring of the system performance and operation for malfunctions; and, (6) alerting the clinician or parent to apnea episodes requiring intervention and to system malfunctions which can adversely affect the integrity of the monitoring process.

As shown in the block diagram of Fig 1(a), the microprocessor controls not only the various system functions and an alarm, but also a speech synthesizer which produces an audible message to alert the clinician or parent to the nature of the system response to a monitored event, (i.e. emergency requiring intervention or a system malfunction). The synthesized message can also provide instructions to the individual overseeing the monitor performance.

Other peripheral equipment illustrated in Fig 1, includes a digital tape drive for preserving a record of the patient's physiological activities. The tape record is available for independent analysis by the clinician at a later date to enable him to periodically redefine the parameters within which the monitor is to operate. The term "parameter" as used herein is intended to include, in the broadest sense, any value under control of an algorithm, or a physician-defined limit, i.e. physiological limits which are prescribed by the clinician for an individual patient and which define a range of normal physiological activity. Typically, the system will be set by the clinician to monitor a physiological

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activity with upper and lower limits on the average rate. For example, the respiratory rate range for newborns might be defined as 30-60 breaths per minute, and the heart rate defined as a rate range of 100-140 beats per minute.

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A rate range may be periodically redefined by the clinician or parent by simply keying in the new parameters on the key pad provided for that purpose. An alpha numeric display is further provided with a menu of instructions for redefining these parameters, and can also be addressed by the microprocessor to display any one of a number of messages (e.g. emergency phone numbers and the like) or such other data which has been or is being collected by the system.

15

Fig 2 provides a flow diagram illustrating an overview of the system processing logic of the multi-channel ventilation monitor which is represented in Fig 1. It is again emphasized that the number of physiological activities which are monitored in this illustration is not to be construed as indicative of the breadth of this invention. Additional physiological activities could also have been included within this illustration, but to do so would introduce additional complexities without enhancement in the ease of understanding or the ultimate level of comprehension.

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In brief, the system logic of this device undergoes "initialization", or what can loosely be described to as "self-test" (lower level system check). This is achieved by setting the various system functions to known states and then confirming that each such system function accurately reflects such known values. Once the system is calibrated in the foregoing manner, it initiates multiple

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sampling of input signals from each of the discrete input channels.

5 The rate of sampling of signal input will differ depending upon the type of sensor which is used to monitor the individual physiological activity. Generally, the input signals which change at a more rapid rate are sampled more frequently than the input signals which change at a relatively lower rate. In the context of the system
10 described in Fig 1, the motion sensor is sampled twenty (20) times per second. In the logic diagram of Fig 2, the respiratory signal is averaged after each four (4) samples of data is received reducing the effective sampling rate to five (5) times per second to provide a more accurate
15 signal trend. Acoustic data is sampled at 6,000 samples per second before digital signal processing derives a set of coefficients (LPC coefficients) which refines the signal to relatively small set of numbers which are representative of predominant frequencies of signal (e.g.
20 derived 20 times per second). The frequency of sampling is an algorithm defined parameter and can be increased or decreased depending upon the system capabilities to process and assimilate the signal input.

25 The order of sampling, analysis and performance of gain check for each of the physiological activities illustrated in Fig 2 has been simplified for the purposes of explanation. In reality, these activities are occurring concurrently along each of the separate channels. The
30 signal processing logic of the system also performs analysis of these discrete channels concurrently and in real-time. Upon completion of sampling of these input signals for each of the monitored physiological activities, a qualitative evaluation of the signal sample
35 for each physiological activity is performed by the alarm

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update system processing logic (Fig 6). If such
qualitative evaluation indicates abnormal activity, an
alarm is triggered. An alarm can be of the type which
dictates intervention to restore breathing; or, simply
5 note an atypical signal or signal pattern without the need
for intervention. The system's logic, thus, has the
ability to effectively differentiate between many abnormal
activity states (specifically denoting any event of
interest) and alert the clinician or parent only to those
10 events which require intervention. This monitor thus
performs a true measurement function, instead of simply
gauging (+) or (-) alarm states. This capability to
discriminate between abnormal signal patterns also
dramatically reduces the frequency of false alarms and,
15 thus, enhances the credibility of the monitor.

Figs 3A and 3B provide an expanded illustration of the
system processing logic for the cardiac signal input.
Because of the relatively complex system processing logic
involved with this physiological activity, this activity
20 has required illustration in two separate figures, Fig 3A
and Fig 3B. It should be emphasized that this cardiac
signal (ballistic cardiogram - BCG) is derived from the
subtle movements associated with cardiovascular activity.
25 The transducer used to detect such movement is the same as
used to detect movement associated with respiratory
activity.

In brief, the cardiac signal system processing logic
30 initially undergoes "normalization" of the signal input to
confirm that the signal is within the range of the
analog/digital converter. This is achieved by
accentuation of the wave form of interest through the
application of certain software filters. If the gain has
35 been improperly set, or the physiological activity is more

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intense than anticipated, the amplitude of the signal may be of too great a magnitude to be accurately monitored. In order to avoid "clipping" of the signal and restore signal amplitude to within the digitizing range, the gain is adjusted accordingly. Similarly, where the system base line is wandering, this is noted so that it may be corrected to insure the appropriate basis of comparison of the amplitude of signal input to data stored in the microprocessor.

Fig 3B is a continuation of Fig 3A from point B. Once the signal has been normalized, the cardiac signal can then be qualitatively evaluated. In the event the cardiac signal quality is poor (e.g. clipped, wandering or noisy) or weak, the system logic will make a gain check adjustment, reset itself, and sample an additional data set. If poor input signal quality persists, the system logic will initiate an alarm sequence indicative of a system malfunction. Where the quality of the cardiac signal is acceptable based upon comparison to established parameters, the system logic is reset for sampling the next set of cardiac signal data. For each new wave of cardiac input data which is detected, the cardiac signal quality timer is reset. Where there is a significant interval between detection of successive cardiac waves, a second gain check adjustment is made and if no new cardiac wave is detected within the interval (parameter) for the cardiac time out, the system logic will set the cardiac status to insufficient signal. Where the cardiac status is determined by the alarm update system logic to be unacceptable, an alarm will be activated.

Assuming that the cardiac signal quality is within acceptable limits and there is essentially continuous flow of new cardiac signal data, the cardiac rate can then be

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compared to the parameters set by the physician or parent. If the rate is too high (tachycardia) the system logic will set the cardiac status to tachycardia alarm. If the heart rate is too low, (bradycardia), the system logic will set the cardiac status to bradycardia alarm. Where the rate of cardiac input is within the parameters set for the monitored activity or perceived to be abnormal, the system logic will perform a gain check adjustment. The shape/pattern of the wave form of the cardiac signal is then analyzed for features which characterize a given wave (period and amplitude), and comparisons made to wave forms of prior cardiac data. Such comparison of characteristic features of the wave form enable the monitor to effectively distinguish between data which is artifact from true cardiac signals. These characteristic wave features are also reviewed by the system logic in its evaluation and identifications of cardiac signal trends. The system logic then proceeds to update the cardiac statistics by averaging the recently obtained data with that previously acquired. It is this averaging of data which enables the system logic to predict trends in cardiac activity and dynamically adjust the gain accordingly.

Fig 4A and Fig 4B provide an expanded illustration of the mattress respiratory signal processing logic of Fig 2. Because of the relative complexity of illustration of this physiological activity, such activity has required expression in two separate figures. Fig 4A illustrates the system logic for "normalization" of the mattress respiratory signal to insure that it is within the range of the analog/digital converter. This process of normalization is analogous to that previously described in the discussion involving the normalization of the cardiac input signal and, thus, need not be repeated here. The

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system logic of Fig 4A performs necessary corrections and adjustments (if any) before the mattress respiratory signal can be qualitatively evaluated.

5 Once these adjustments are effected, to the extent required, the mattress respiratory signal quality is evaluated. Where the signal is clipped, wandering or noisy, the system logic will make a gain check adjustment, reset itself and sample an additional data set. If poor
10 respiratory input signal quality persists, the system logic will set the respiratory status as indicative of a system malfunction (insufficient mattress respiratory signal).

15 Where the quality of respiratory mattress signal is perceived as adequate, the system logic is reset for sampling of the next set of mattress respiratory data. For each new wave of mattress respiratory data which is detected, the mattress respiratory signal quality timer is
20 reset. Where there is a relatively long interval between detection of successive mattress respiratory waves, a second gain check adjustment is made and if no new mattress respiratory wave is detected within the interval for the mattress respiratory time out, the system logic
25 will set the mattress respiratory status to apnea alarm. If the mattress respiratory status is determined by the alarm update system logic to be outside of accepted limits set for respiratory activity, an alarm will be activated.

30 Assuming that mattress respiratory signal quality is within acceptable limits and there is an essentially continuous flow of new mattress respiratory signal data, the mattress respiratory rate can then be compared to parameters set by the physician or parent. If the
35 respiratory rate is too high (tachypnea), the system logic

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will set the mattress respiratory status to tachypnea alarm. If the respiration rate is too low, (bradypnea) the system logic will set the mattress respiration status to bradypnea alarm. The shape/pattern of the wave form of the respiratory signal is analyzed for features which characterize a given wave (i.e. period and amplitude), and comparison made to the wave form of prior respiratory data. Such comparison of the characteristic features of the wave form enable the monitor to effectively distinguish between data which is artifact from true respiratory signals. The characteristic wave features are also received by the system logic in its evaluation of and identification of respiratory signal trends. For example, this pattern recognition of the wave form of the respiratory signals enables characterization of a sequence of respiratory waves as representative of normal breathing or as representative of a pathological breathing pattern, e.g. Cheyne-Stokes breathing. Whether the respiration rate is within the parameters set for the monitored activity or perceived to be abnormal, the system logic will perform a gain check adjustment.

Fig 5 is an expanded illustration of the audio-based respiratory signal processing logic of Fig 2. This signal is derived from the linear predictive coefficients discussed previously. In brief, the audio-based respiratory signal is "normalized" to insure that it is within the range of analog to digital convertor. This normalization process is analogous to that previously described for the cardiac input signal and, thus, need not be repeated. Once the signal has been normalized, it is qualitatively evaluated. This qualitative evaluation involves determination of the strength and adequacy of the signal and execution of a gain check adjustment. If a weak or an inadequate signal persists, the system logic

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will set the audio status to indicate an insufficient audio-based respiratory signal. Where, however, the audio-based respiratory signal is deemed adequate, the system logic is reset for sampling the next set of audio-based respiratory data. The system logic will then reset the signal quality timer and sample an additional data set. For each new wave of audio-based respiratory data which is detected, the audio respiratory signal quality timer is reset. Where there is a relatively long interval between detection of successive audio respiratory waves, a second gain check adjustment is made. If no new audio-based respiratory wave is detected within the interval for the obstructive apnea timeout, the system logic will set the audio-based respiratory status to obstructive apnea alarm. If the audio-based respiratory signal status is determined by the alarm update system logic to be outside of the accepted limits set for the audio respiratory activity, an alarm will be activated. Assuming that the audio-based respiratory signal is within acceptable limits and there is essentially a continuous flow of new waves of new audio-based respiratory signal data, the obstructive apnea timer will be reset. The system logic will also use the acceptable mattress and audio-based respiratory signal data to update the respiratory statistics in the microprocessor memory. Such updating of statistics enables the microprocessor to plot trends in such data.

Fig 6 is an expanded illustration of the alarm update signal processing logic of Fig 2. In brief, the alarm update simply checks the mattress and audio respiratory status alarm. If the respiratory signal is perceived to be abnormal, an alarm is activated by the alarm update system logic. Similarly, the alarm update system logic checks the cardiac status alarm. If any unusual status

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has been set, then an alarm is activated. The system logic can also assign alarm state priorities. In the preferred configuration of the system of this invention, the system logic will "arbitrate" between different alarm states before implementing a decision to initiate an alarm.

Fig 7 is an expanded illustration of the signal processing logic for the gain check adjustment of Fig 2. The signal processing logic of the gain check adjustment will initially determine when the last gain check was made. If a prescribed time interval has expired, the system will perform a gain check in order to confirm that the data sampling is occurring within the parameters set for the system. The system will also check to determine if a clipping error has occurred since the last gain check; namely, whether or not a portion of the signal is outside the parameters set for the signal by the system. If in fact clipping is occurring, the system logic will determine if the gain is already at the minimum. If in fact it is at the minimum, no further gain reduction can be performed. If the gain is not at the minimum when clipping is detected, the system logic will reduce the gain and then rescale the signal parameters accordingly. Where no clipping of the signal is occurring, the system logic will determine if the signal amplitude is less than ideal for the sampling of the input data. Where the signal amplitude is less than ideal and the gain is already set at its maximum, no further gain increase can be performed. Where the gain is not at the maximum and the signal amplitude is less than ideal, the system logic will increase the gain and then rescale the signal parameters accordingly. Where the signal amplitude is set within the range set for such parameters, the signal parameters will not be rescaled. The gain check

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adjustments are permitted by the above system logic only when such changes can be made without triggering an erroneous alarm, i.e., when the signal is at or near the base-line, (zero voltage).

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The information (data sets), upon which the above system logic can operate, is preferably generated by a transducer within a mattress and one or more microphones, which have been strategically positioned to receive audible sounds indicative of breathing activity. The mattress transducer suitable for use in the device of this invention can be of the type described by Lewiner et al in U.S. Patent 4,359,726 and by Fraden in U. S. Patent 4,509,527. The preferred configuration of this device incorporates a piezoelectric film of polyvinylidene fluoride. This transducer is capable of sensing the motion associated with both respiratory and cardiovascular activity (ballistic cardiogram). An alternative, or companion to the foregoing transducer, is a strain gauge type sensor which can be incorporated into the mattress or attached directly to the monitored subject.

The detection of audible sounds associated with breathing/choking can be accomplished with one or more microphones which have been strategically positioned relative to the monitored subject. Where, a single microphone is used, its design and placement need be more exact so as to focus its sound-collection capabilities upon the source of acoustic input. This can be achieved through design of the microphone itself (i.e. parabolic microphone) or by shielding the monitored field from extraneous sounds.

Alternatively, the detection of audible sounds can be achieved with a microphone array. With this type of

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microphone configuration, it is possible to emphasize the desirable acoustic information while at the same time attenuating and/or distorting the unwanted speech or random noise. This is achieved by application of well-known nonlinear signal processing techniques (either preprocessing the analog signals or utilizing techniques that are classified as digital signal processing) to the outputs of two or more microphones (known as a microphone array). The processing of the microphone signals, results in an output signal which enhances the on-center (crib) sounds. This class of nonlinear signal processors, for the outputs of an array of microphones, emphasizes sounds coming from a particular (on-center) location against a background of other sounds. These processes completely eliminate any off-center impulsive noise which is non-overlapping at the microphones.

The approach of deriving a single audio signal, via analog preprocessing, depends upon each microphone in the array simultaneously receiving the wanted signal, thus requiring delay and gain adjustments unless the effects of these parameters are negligible. If the effects of gain and delay are not negligible, then digital signal processing is required. The digital signal processing of a microphone array permits the delay and gain adjustments to be mathematically performed by the computer program.

In a ventilation monitor of the type contemplated by this invention, the array processor utilizes a variation of the class of nonlinear signal processors described in an article by O. M. M. Mitchell, et. al., "Signal Processing for a Cocktail Party Effect", J. Acoustic Soc. Amer. Vol. 50, No. 2 (Part 2), pp. 656-660, August 1971. The output signal of a nonlinear processor of this type is given by the equation:

- 25 -

$$S = v_1 + v_2 + v_3 + v_4 - |v_1 - v_2| - |v_3 - v_4| + \\ |v_1 + v_2 - v_3 - v_4| - |v_1 - v_2| + |v_3 - v_4|$$

5 where v_1 , v_2 , v_3 , and v_4 are the four (4) microphone inputs.

The output appears complicated, but the output S is always exactly equal to four times sum of the inputs and is given by the following relations:

10

$$s_1 = \min (v_1, v_2) \quad \text{and} \quad s_2 = \min (v_3, v_4)$$

$$\text{thus } S = 4 * \max (s_1, s_2).$$

15 The above relationships expressed in the foregoing equations may be summarized as follows: the output S is four times the greater of two quantities s_1 and s_2 ; where s_1 is the lessor of the inputs v_1 and v_2 , and s_2 is the lessor of the inputs v_3 and v_4 . In effect, the nonlinear
20 processor "looks" at only one input at a time and ignores all of the others.

In addition to the motion and acoustic sensors described above, this system is compatible with other sensors
25 commonly used for monitoring physiological activities associated with respiration and other vital physiological functions. For example, the above device can also incorporate and process information obtained from additional sensors such as an impedance belt,
30 transcutaneous sensors, (for PO_2 and PCO_2) and a thermometer. It is to be emphasized that these additional sensors are not contemplated as a replacement for either the motion or acoustic sensors described previously. As will also be appreciated, these additional sensors require
35 (to a greater or lessor degree) more intimate physical

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contact with the monitored subject than do the preferred motion and acoustic sensors of the device previously described. Under certain circumstances, it may, however, be desirable to incorporate the motion sensor of the preferred device into a harness to be worn by the monitored subject. For example, when the monitored subject is to be taken out of the hospital or home environment, a motion sensor incorporated within a harness, in conjunction with a portable monitor, may be the only practical way to maintain continuous surveillance of the monitored subject, (i.e. an infant). Of course, if the remote environment (i.e. carriage) were equipped with a motion sensor within a mattress, such a harness would be unnecessary.

In order to permit a degree of mobility to the monitored subject, the most preferred ventilation monitor of this invention contemplates both an integrated main, or base station (6) and a modular, or portable unit (8), of the type illustrated in Figure 8. The main unit of the monitor illustrated in Figure 8 includes a housing (10) for the electronic circuitry and microprocessor (not shown) which are required to process the data acquired during the monitoring of the patient. The front panel (12) of the housing (10) includes a display (14), function keys (16), accommodation (18) for a tape drive recorder (not shown) and accommodation (20) for docking a portable monitor (8). This portable monitor (22) is maintained within the main unit (6) during monitoring in the home or hospital environment. The main and portable units are maintained in a communicative relationship to one another via a ribbon connector (24) so as to insure that the microprocessor within each such unit is kept current as to the data associated the respiratory movements of the monitored subjects. Accordingly, when the patient is to

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be removed from the hospital or home environment, the portable unit (8) will be able to provide continuous monitoring of the patient. When a patient has returned to the hospital or home environment, the portable unit is redocked with the main station and all data recorded by the portable unit communicated to the microprocessor of the main station. Thus, the most preferred embodiment of this invention provides an effective means for continuous monitoring of the patient both in the environment of the base station and at a location which is remote from the base station.

The ventilation monitor of this invention also contemplates the utilization of additional pieces of peripheral equipment. For example, in the event an alarm state is detected, the microprocessor of the main unit has the capacity to communicate such information to a remote terminal. In addition, a separate tape drive can also be wired to the main unit to record data on the monitored subject or transmit such data via a modem to a computer or tape drive at a remote location.

As is evident from the foregoing description, the ventilation monitor of this invention possesses a degree of versatility and sophistication presently unavailable in prior art systems. It is, however, apparent that certain changes, additions or improvements may be made to this device without departure from the spirit or scope of this invention, which is set forth in the following claims.

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WHAT IS CLAIMED IS:

1. A multi-channel ventilation monitor for real-time monitoring of multiple physiological activities associated with respiration of a monitored subject, involving comparison of a plurality of discrete data signals indicative of each such activity, said monitor comprising:
- (a) a plurality of sensors, each of which being capable of detection of a discrete physiological activity associated with breathing activity and capable of generation of data signals which are characteristic of each of the sensed physiological activity;
- (b) a plurality of discrete information processing channels, each of said channels being associated with and capable of processing a data signal indicative of each such physiological activity;
- (c) a signal processing means associated with each such channel for verifying the quality of each such signal;
- (d) means for dynamic adjustment of the gain and frequency response for each of the sensed physiological activity to reflect trends in the data signal for each such physiological activity;
- (e) means for comparison of the wave form of each such signal to certain standards, including wave forms of a sensed physiological activity which have been stored in a data base and wave forms of sensed physiological activity which are indicative of a trend in a sensed activity for the monitored subject; and

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(f) means for generation of an output signal to indicate abnormal physiological activity associated with respiration.

5 2. The monitor of claim 1, wherein the sensors include a motion detector, contained within a mattress, and an acoustic sensor for detection of audible sounds associated with breathing activity.

10 3. The monitor of claim 1, wherein the means for adjustment in the gain of the data signal for each of the sensed physiological activities is responsive to changes in the level of the sensed physiological activity.

15 4. The monitor of claim 1, wherein the means for comparison of the wave form of the signal data to wave forms which are stored in a data base enables the monitor to effectively differentiate between a data signal which is indicative of a sensed physiological activity and a
20 data signal which is artifact.

5. A multi-channel ventilation monitor for real time monitoring of multiple physiological activities associated with respiration and cardiovascular movement of a
25 monitored subject, involving comparison of a plurality of discrete data signals indicative of each such activity, said monitor comprising:

30 (a) a plurality of sensors, at least one of which being capable of detection of movement associated with respiratory activity and another of which being capable of detection of movement associated with cardiovascular activity, and the generation of data signals which are characteristic of each of the sensed physiological
35 activity;

- 30 -

(b) a plurality of discrete information processing channels, each of said channels being associated with and capable of processing a data signal indicative of each such physiological activity;

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(c) a signal processing means associated with each such channel for verifying the quality of each such signal;

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(d) means for dynamic adjustment of the gain and frequency response for each of the sensed physiological activity to reflect trends in the data signal for each such physiological activity; and

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(e) means for comparison of the wave form of each such signal to certain standards, including wave forms of a sensed physiological activity which have been stored in a data base and wave forms of sensed physiological activity which are indicative of a trend in a sensed activity for the monitored subject; and

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(f) means for generation of an output signal indicative of abnormal movement associated with breathing and/or cardiovascular activity.

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6. The monitor of claim 5, wherein the sensors include a motion detector, contained within a mattress, and an acoustic sensor for detection of audible sounds associated with breathing activity.

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7. The monitor of claim 5, wherein the means for adjustment in the gain of the data signal for each of the sensed physiological activities is responsive to changes in the level of the sensed physiological activity.

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8. The monitor of claim 5, wherein the means for comparison of the wave form of the signal data to wave forms which are stored in a data base enables the monitor to effectively differentiate between a data signal which is indicative of a sensed physiological activity and a data signal which is artifact.

9. In a ventilation monitor, equipped with signal data processing capability, which is designed for measurement of the plurality of physiological activities associated with respiration by detection of sensations indicative of respiration, the improvement comprising:

(a) variable signal amplifiers capable of either increasing or decreasing the amplitude of a data signal; and

(b) means for dynamic adjustment of the gain of the variable signal amplifiers in response to changes in the level of the monitored physiological activity, so as to insure that such data signal is of optimum signal intensity, for each of the monitored physiological activities, to enable continuous monitoring of the subject without activation of a false alarm;

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10. In a ventilation monitor, equipped with signal data processing capability, which is designed for measurement of the plurality of physiological activities associated with respiration by detection of sensations indicative of respiration, the improvement comprising:

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(a) adjustable low-pass and/or band-pass filters for enhancement the data signal of interest; and

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(b) means for dynamic adjustment of the frequency response of the low-pass and band-pass filters in response to changes in the level of the monitored physiological activity, to reflect trends in signal data for each such physiological activity.

11. In a ventilation monitor designed for measurement of the plurality of physiological activities associated with respiration by detection of sensations indicative of breathing and the activation of an alarm where one or more of such activities is perceived to be abnormal, the improvement comprising:

(a) means for assignment of priorities among the various perceived abnormal activity states; and

(b) means for arbitration between the various abnormal activity states, based upon assignment of priorities, prior to the initiation of an alarm.

12. A multi-channel ventilation monitor for real-time monitoring of multiple physiological activities associated with respiration by measurement of the immediate ambient environment of the monitored patient for discrete data signals indicative of each such activity state, said monitor comprising:

(a) a plurality of sensors, each of which being capable of detection, within the immediate ambient environment of the monitored subject, discrete physiological activities associated with breathing activity, and capable of generation of signal data which are characteristic of the sensed physiological activities;

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(b) a plurality of discrete information processing channels, each of said channels being associated with and capable of processing a data signal indicative of each such physiological activity;

5

(c) a signal processing means associated with each such channel for verifying the quality of each such signal;

10 (d) means for dynamic adjustment of the gain and frequency response for each of the sensed physiological activity to reflect trends in the data signal for each such physiological activity; and

15 (e) means for comparison of the wave form of each such signal to certain standards, including wave forms of a sensed physiological activity which have been stored in a data base and wave forms of sensed physiological activity which are indicative of a trend in a sensed
20 activity for the monitored subject; and

(f) means for generation of an output signal to indicate abnormal physiological activity associated with respiration.

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13. The monitor of claim 12, wherein the sensors include a motion detector, contained within a mattress, and an acoustic sensor for detection of audible sounds associated with breathing activity.

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14. The monitor of claim 12, wherein the means for adjustment in the gain of the data signal for each of the sensed physiological activities is responsive to changes in the level of the sensed physiological activity.

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15. The monitor of claim 12, wherein the means for comparison of the wave form of the signal data to wave forms which are stored in a data base enables the monitor to effectively differentiate between a data signal which is indicative of a sensed physiological activity and a data signal which is artifact.

16. In a ventilation monitor designed for measurement of a plurality and physiological activities associated with respiration of a monitored subject by detection of sensations indicative of breathing, the improvement comprising:

(a) means for detection of a plurality of discrete physiological activities of the monitored subject by sensing the immediate ambient environment of the monitored subject and generation of signal data which are characteristic of the sensed physiological activities; and

(b) means for analysis of the wave form of each wave of signal data for characteristic features of the wave form and comparison of each such wave form to the wave form of prior signal data so as to enable the monitor to distinguish between signal data which is indicative of physiological activities and signal data which is indicative of artifact.

17. In a method for real-time monitoring of multiple physiological activities associated with respiration of a monitored subject, involving sensing of the physiological activity, generation of a data signal indicative of such physiological activity, processing of the data signal and comparison of the data signal to certain standards and/or physician defined parameters, the improvement comprising:

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(a) providing

5 (i) a plurality of sensors, each of which being capable of detection of a discrete physiological activity associated with breathing activity and capable of generation of data signals which are characteristic of each of the sensed physiological activity;

10 (ii) a plurality of discrete information processing channels, each of said channels being associated with and capable of processing a data signal indicative of each such physiological activity; and

15 (iii) a signal processing means associated with each such channel for verifying the quality of each such signal;

20 (b) sensing a plurality of physiological activities associated with breathing activity and generation of data signals indicative of each such activity;

25 (c) dynamically adjusting the gain and frequency response for each of the sensed physiological activity to reflect trends in the data signal for each such physiological activity;

30 (d) comparing the wave form of each such signal to certain standards, including wave forms of a sensed physiological activity which have been stored in a data base and wave forms of sensed physiological activity which are indicative of a trend in a sensed activity for the monitored subject; and

35 (e) generating an output signal to indicate abnormal physiological activity associated with respiration.

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18. An apparatus which includes a base station monitor comprising a housing, means for docking of a portable monitor within said housing, means for permitting communication of data between a microprocessor of said base station monitor and a microprocessor of said portable monitor when the portable monitor is docked within the housing.

19. A multi-channel ventilation monitor for real-time monitoring of multiple physiological activities associated with respiration of a monitored subject, involving comparison of a plurality of discrete data signals indicative of each such activity, said monitor comprising:

(a) at least one sensors capable of detection of a discrete physiological activity associated with breathing activity and capable of generation of data signals which are characteristic of each of the sensed physiological activity;

(b) one or more discrete information processing channels, each of said channels being associated with and capable of processing a data signal indicative of each such physiological activity;

(c) a signal processing means associated with each such channel for verifying the quality of each such signal;

(d) means for dynamic adjustment of the gain and frequency response for each of the sensed physiological activity to reflect trends in the data signal for each such physiological activity;

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20. The monitor of claim 19, wherein the sensor comprises a motion detector contained within a mattress.

5 21. The monitor of claim 19, wherein the means for adjustment in the gain of the data signal for each of the sensed physiological activities is responsive to changes in the level of the sensed physiological activity.

10 22. The monitor of claim 19, wherein the means for comparison of the wave form of the signal data to wave forms which are stored in a data base enables the monitor to effectively differentiate between a data signal which is indicative of a sensed physiological activity and a data signal which is artifact.

15 23. A multi-channel ventilation monitor for real time monitoring of multiple physiological activities associated with respiration and cardiovascular movement of a monitored subject, involving comparison of a plurality of
20 discrete data signals indicative of each such activity, said monitor comprising:

(a) at least one sensor capable of detection of movement associated with respiratory activity and of
25 movement associated with cardiovascular activity, and the generation of data signals which are characteristic of each of the sensed physiological activity;

(b) a plurality of discrete information processing
30 channels, each of said channels being associated with and capable of processing a data signal indicative of each such physiological activity;

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(c) a signal processing means associated with each such channel for verifying the quality of each such signal;

5 (d) means for dynamic adjustment of the gain and frequency response for each of the sensed physiological activity to reflect trends in the data signal for each such physiological activity; and

10 (e) means for comparison of the wave form of each such signal to certain standards, including wave forms of a sensed physiological activity which have been stored in a data base and wave forms of sensed physiological activity which are indicative of a trend in a sensed
15 activity for the monitored subject; and

(f) means for generation of an output signal indicative of abnormal movement associated with breathing and/or cardiovascular activity.

20

24. The monitor of claim 23, wherein the sensor comprises a motion detector contained within a mattress.

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25. The monitor of claim 23, wherein the means for adjustment in the gain of the data signal for each of the sensed physiological activities is responsive to changes in the level of the sensed physiological activity.

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26. The monitor of claim 23, wherein the means for comparison of the wave form of the signal data to wave forms which are stored in a data base enables the monitor to effectively differentiate between a data signal which is indicative of a sensed physiological activity and a data signal which is artifact.

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27. A multi-channel ventilation monitor for real-time monitoring of multiple physiological activities associated with respiration by measurement of the immediate ambient environment of the monitored patient for discrete data signals indicative of each such activity state, said monitor comprising:

(a) at least one sensor capable of detection, within the immediate ambient environment of the monitored subject, discrete physiological activities associated with breathing activity, and capable of generation of signal data which are characteristic of the sensed physiological activities;

(b) a plurality of discrete information processing channels, each of said channels being associated with and capable of processing a data signal indicative of each such physiological activity;

(c) a signal processing means associated with each such channel for verifying the quality of each such signal;

(d) means for dynamic adjustment of the gain and frequency response for each of the sensed physiological activity to reflect trends in the data signal for each such physiological activity; and

(e) means for comparison of the wave form of each such signal to certain standards, including wave forms of a sensed physiological activity which have been stored in a data base and wave forms of sensed physiological activity which are indicative of a trend in a sensed activity for the monitored subject; and

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- 40 -

(f) means for generation of an output signal to indicate abnormal physiological activity associated with respiration.

5 28. The monitor of claim 27, wherein the sensor comprises a motion detector contained within a mattress.

10 29. The monitor of claim 27, wherein the means for adjustment in the gain of the data signal for each of the sensed physiological activities is responsive to changes in the level of the sensed physiological activity.

15 30. The monitor of claim 27, wherein the means for comparison of the wave form of the signal data to wave forms which are stored in a data base enables the monitor to effectively differentiate between a data signal which is indicative of a sensed physiological activity and a data signal which is artifact.

20 31. In a method for real-time monitoring of multiple physiological activities associated with respiration of a monitored subject, involving sensing of the physiological activity, generation of a data signal indicative of such physiological activity, processing of the data signal and
25 comparison of the data signal to certain standards and/or physician defined parameters, the improvement comprising:

(a) providing

30 (i) at least one sensor capable of detection of a discrete physiological activity associated with breathing activity and capable of generation of data signals which are characteristic of each of the sensed physiological activity;

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(ii) a plurality of discrete information processing channels, each of said channels being associated with and capable of processing a data signal indicative of each such physiological activity; and

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(iii) a signal processing means associated with each such channel for verifying the quality of each such signal;

10

(b) sensing a plurality of physiological activities associated with breathing activity and generation of data signals indicative of each such activity;

15

(c) dynamically adjusting the gain and frequency response for each of the sensed physiological activity to reflect trends in the data signal for each such physiological activity;

20

(d) comparing the wave form of each such signal to certain standards, including wave forms of a sensed physiological activity which have been stored in a data base and wave forms of sensed physiological activity which are indicative of a trend in a sensed activity for the monitored subject; and

25

(e) generating an output signal to indicate abnormal physiological activity associated with respiration.

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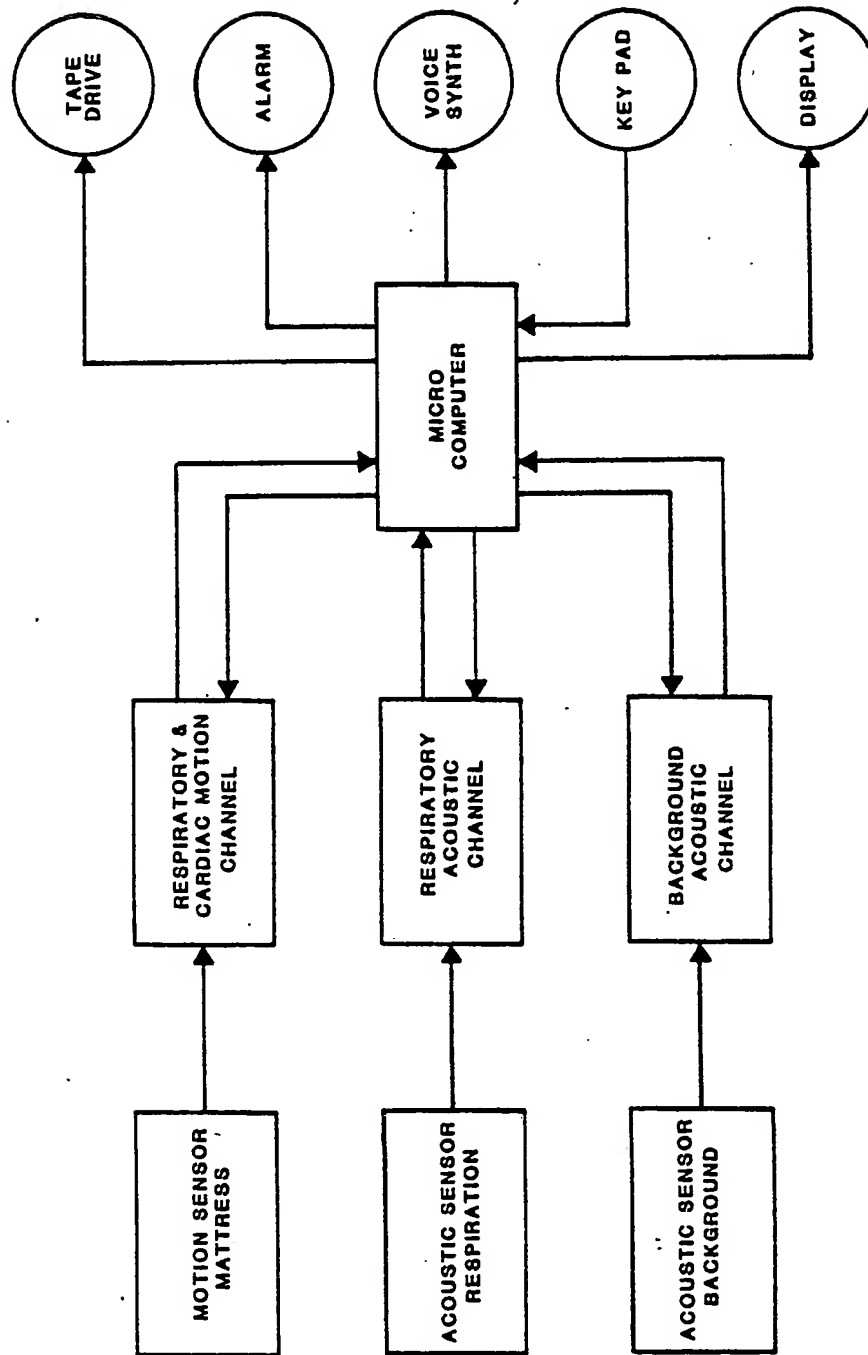


Figure 1A

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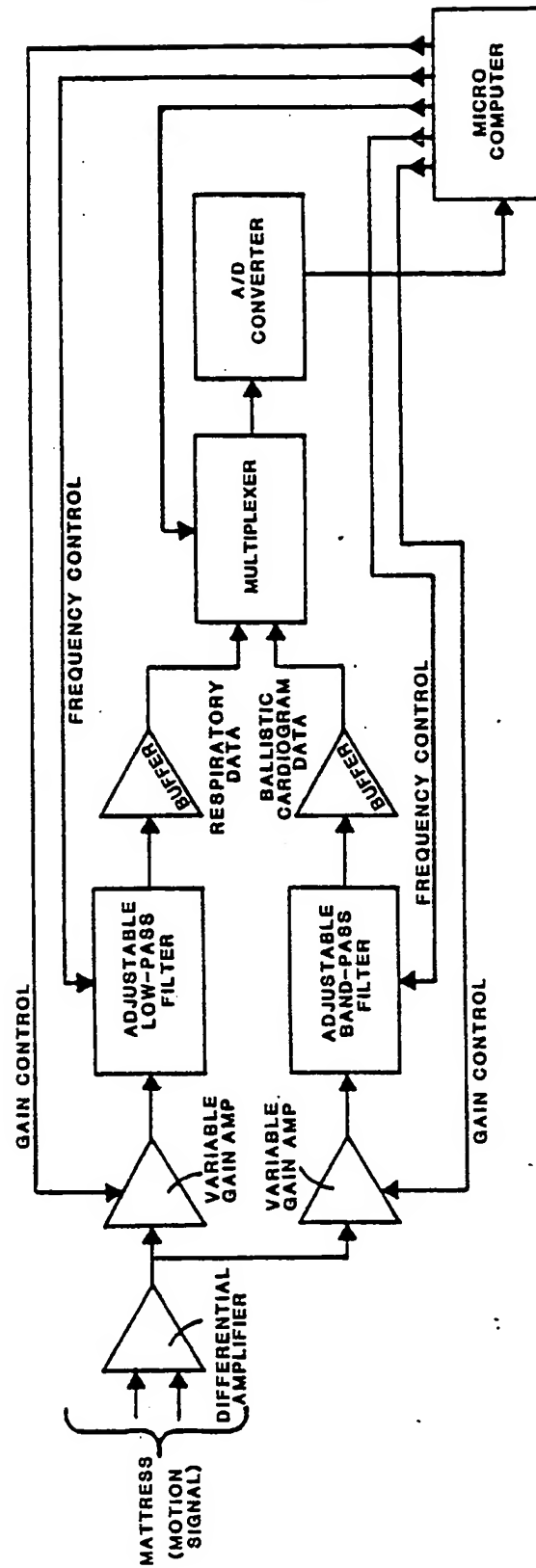


Figure 1B

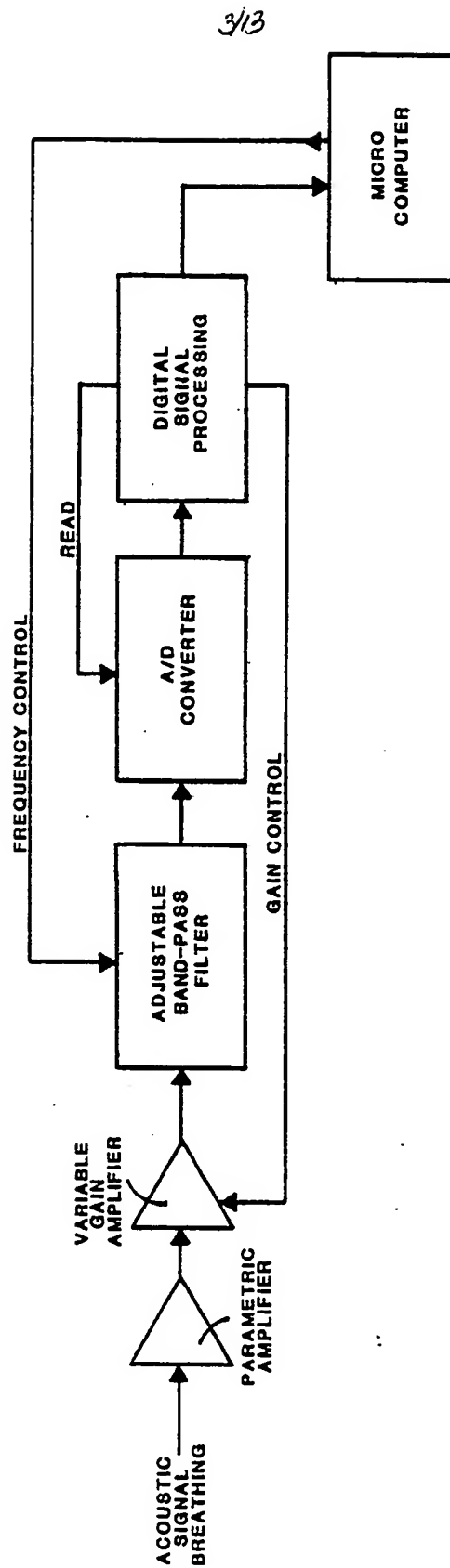


Figure 1C

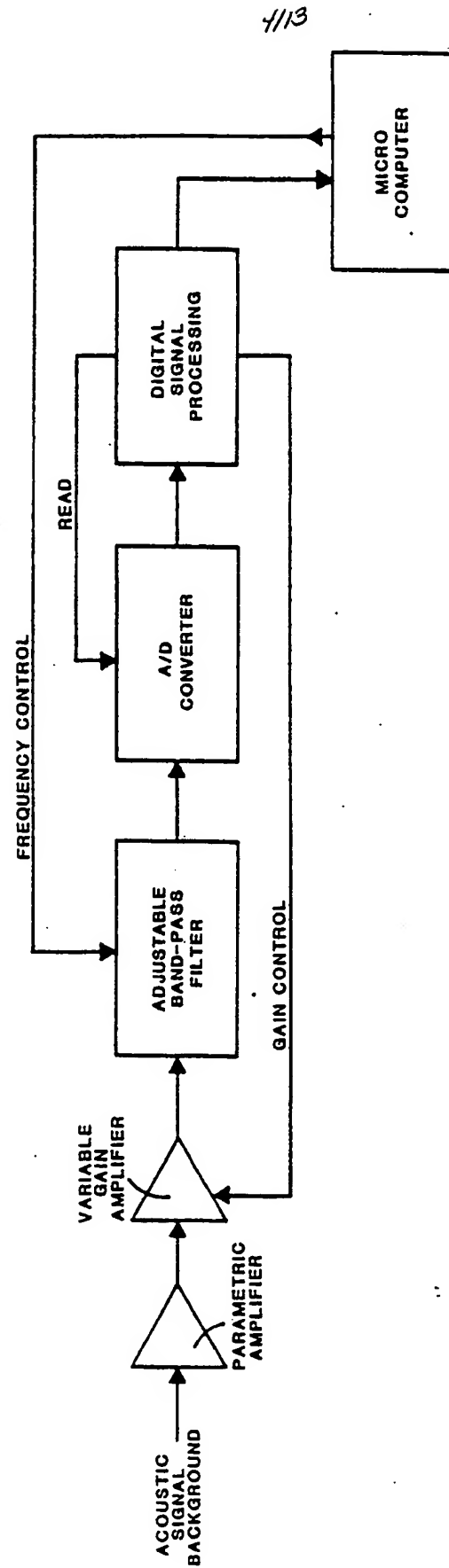
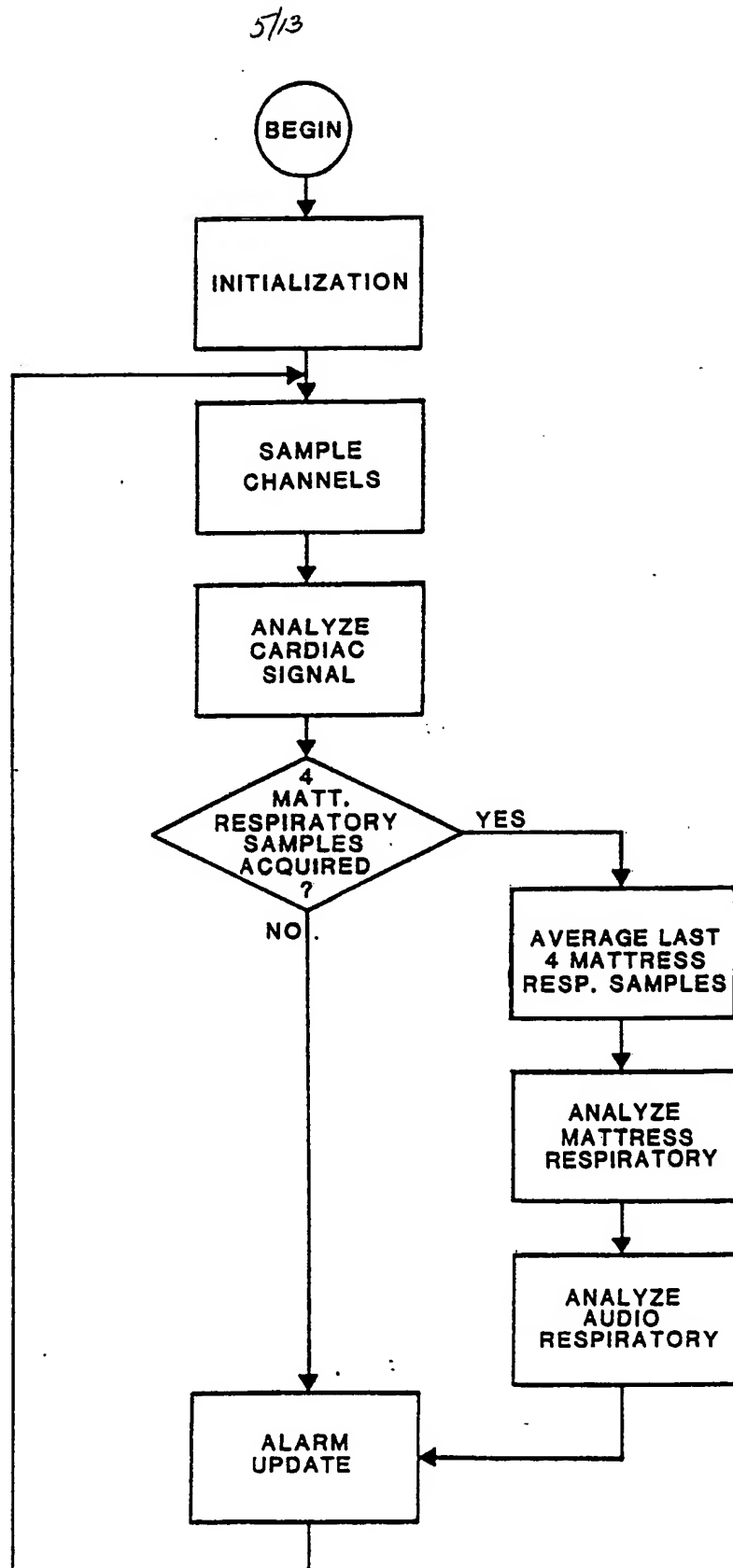


Figure 1D

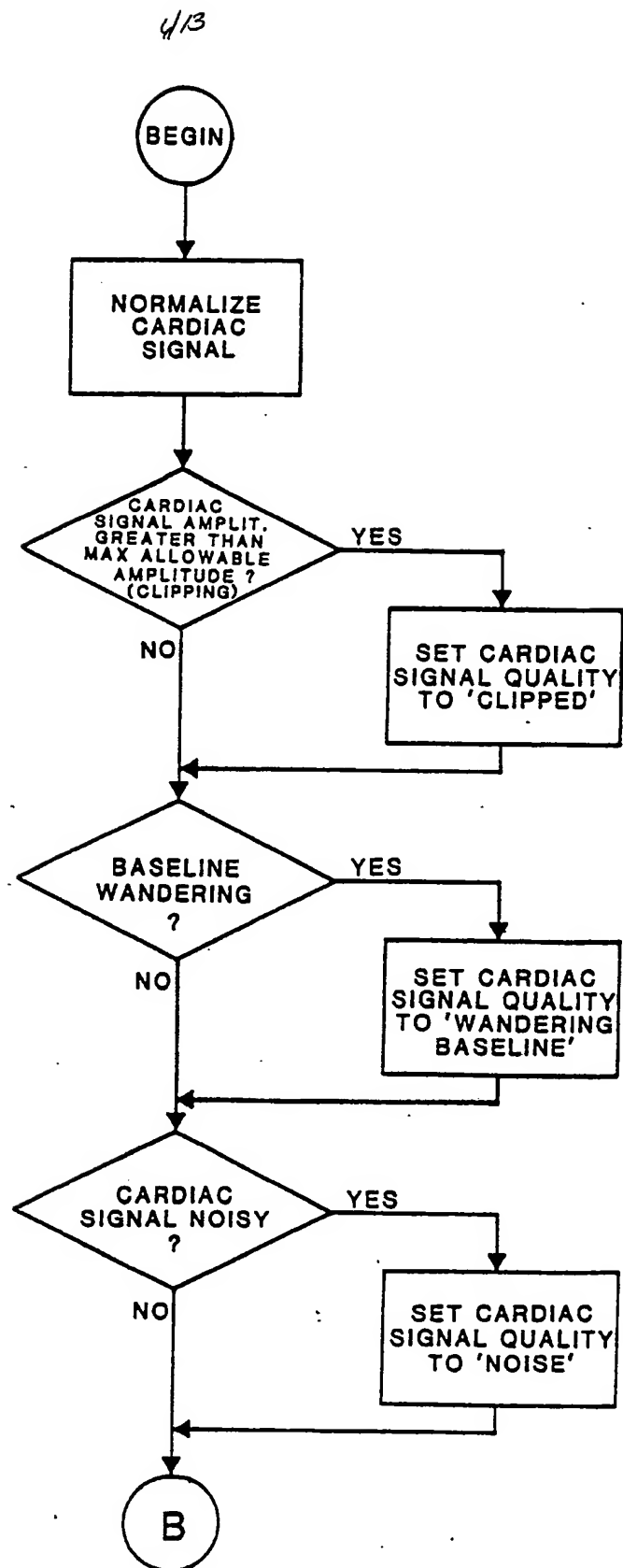
System
Overview

Figure 2



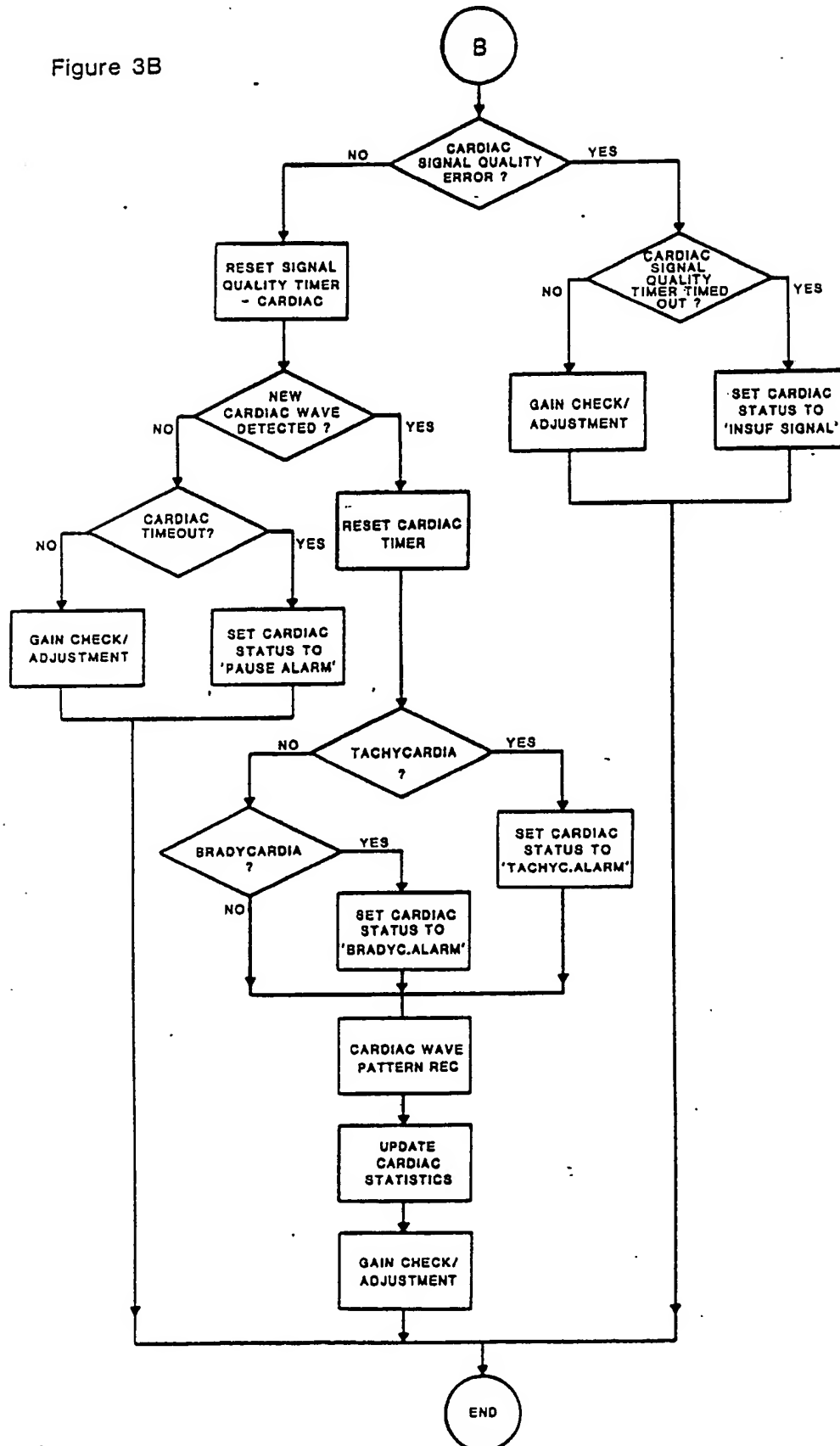
Analyze
Cardiac
Signal

Figure 3A



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Figure 3B



Analyze
Mattress Respiratory
Signal

Figure 4A

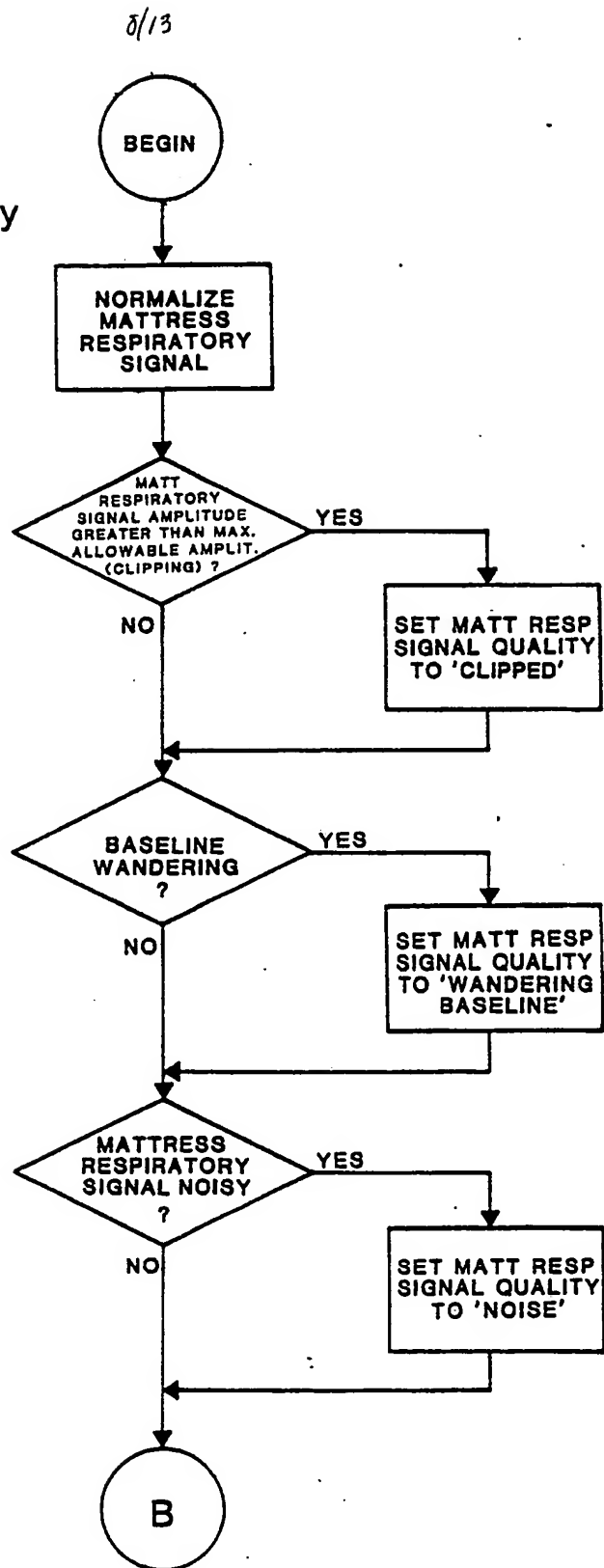
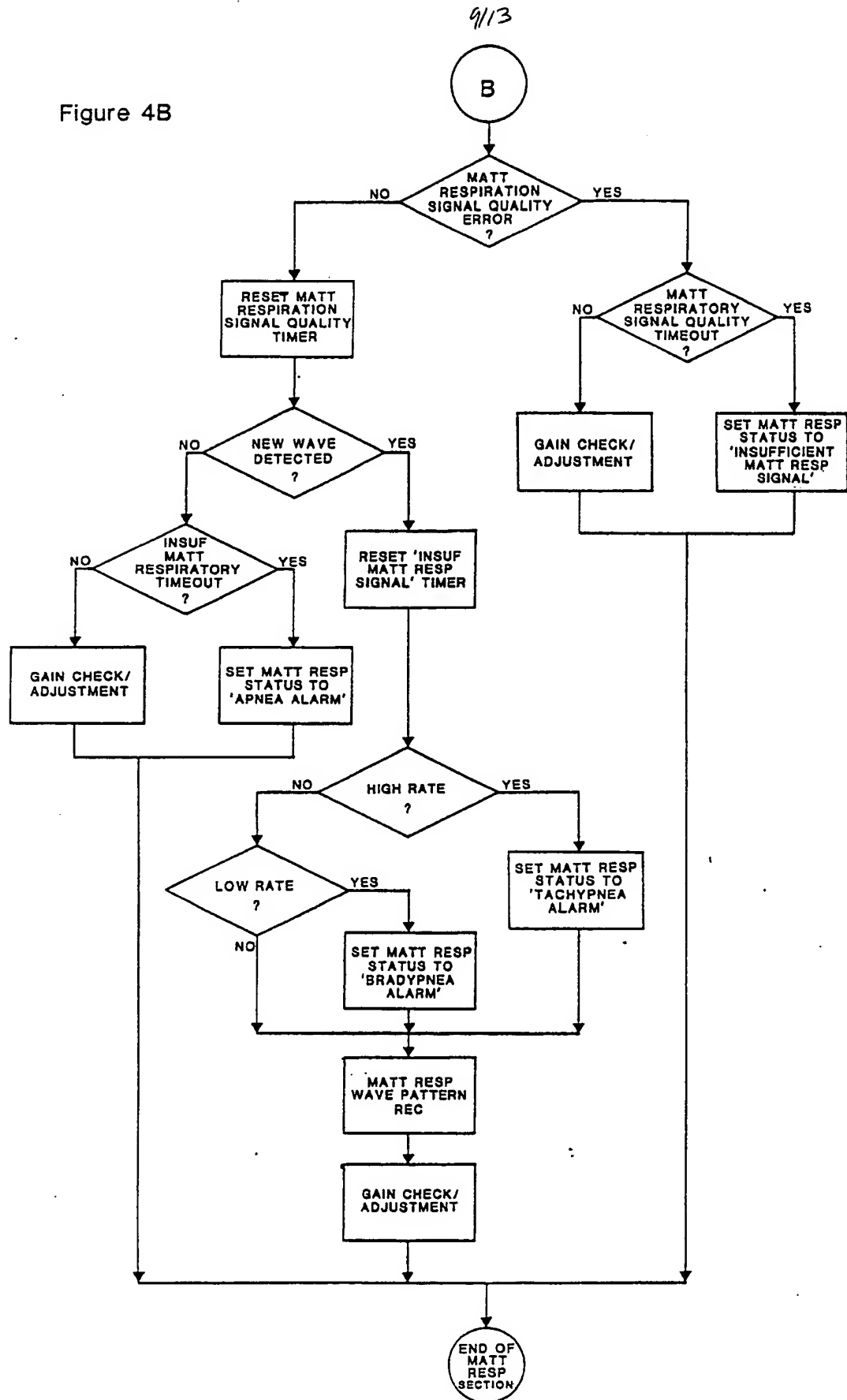
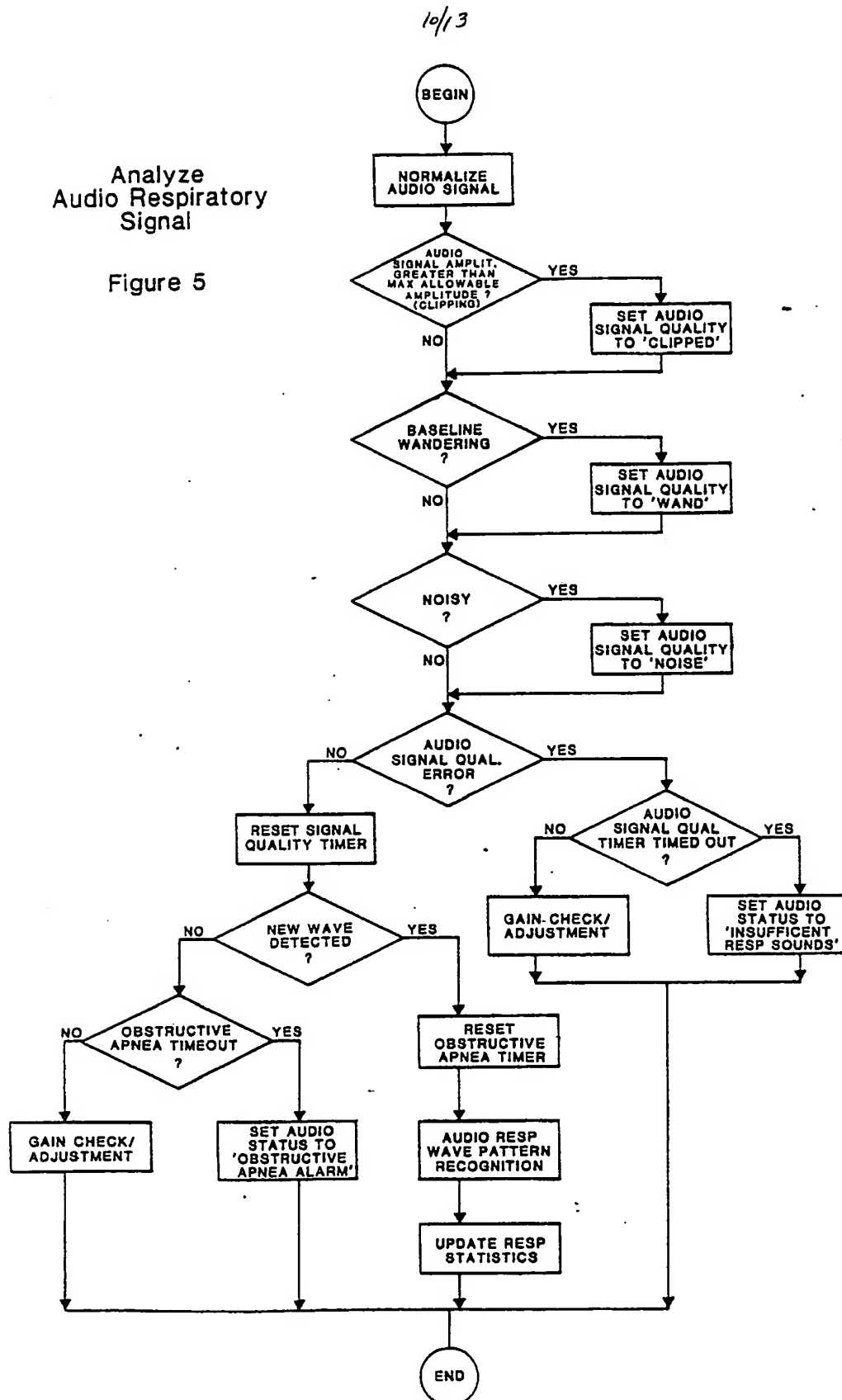


Figure 4B



Analyze
Audio Respiratory
Signal

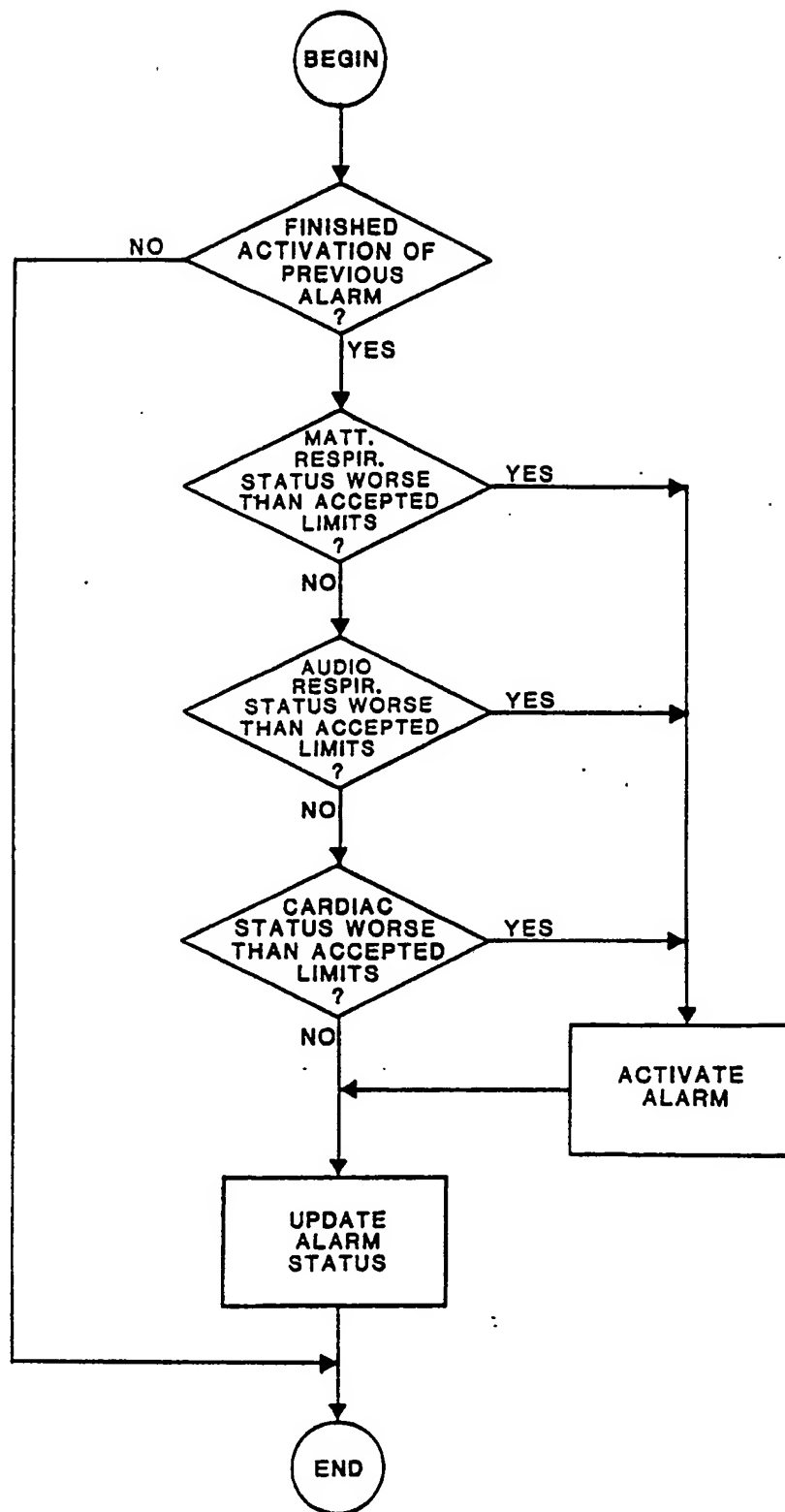
Figure 5



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Alarm
Update

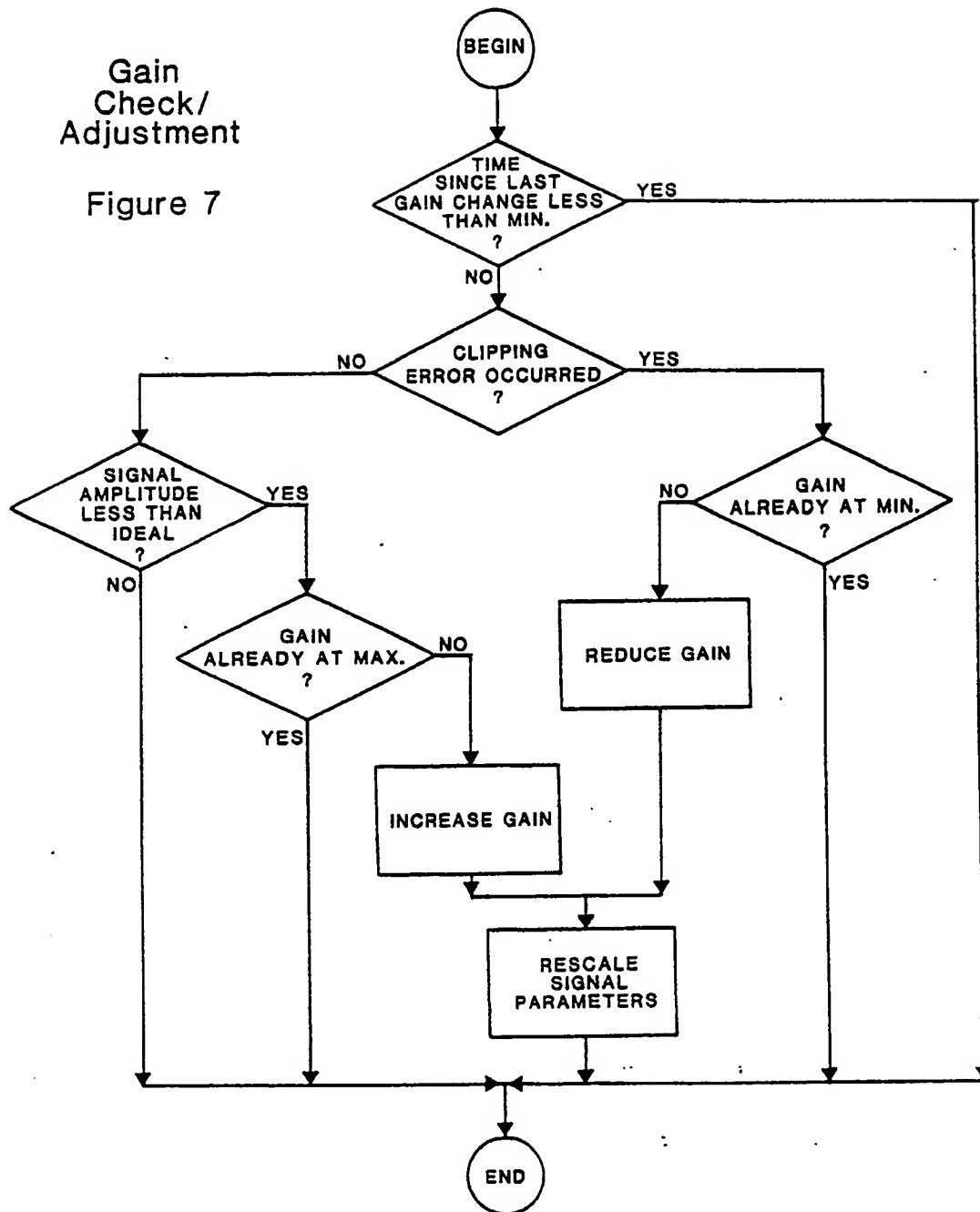
Figure 6



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Gain
Check/
Adjustment

Figure 7



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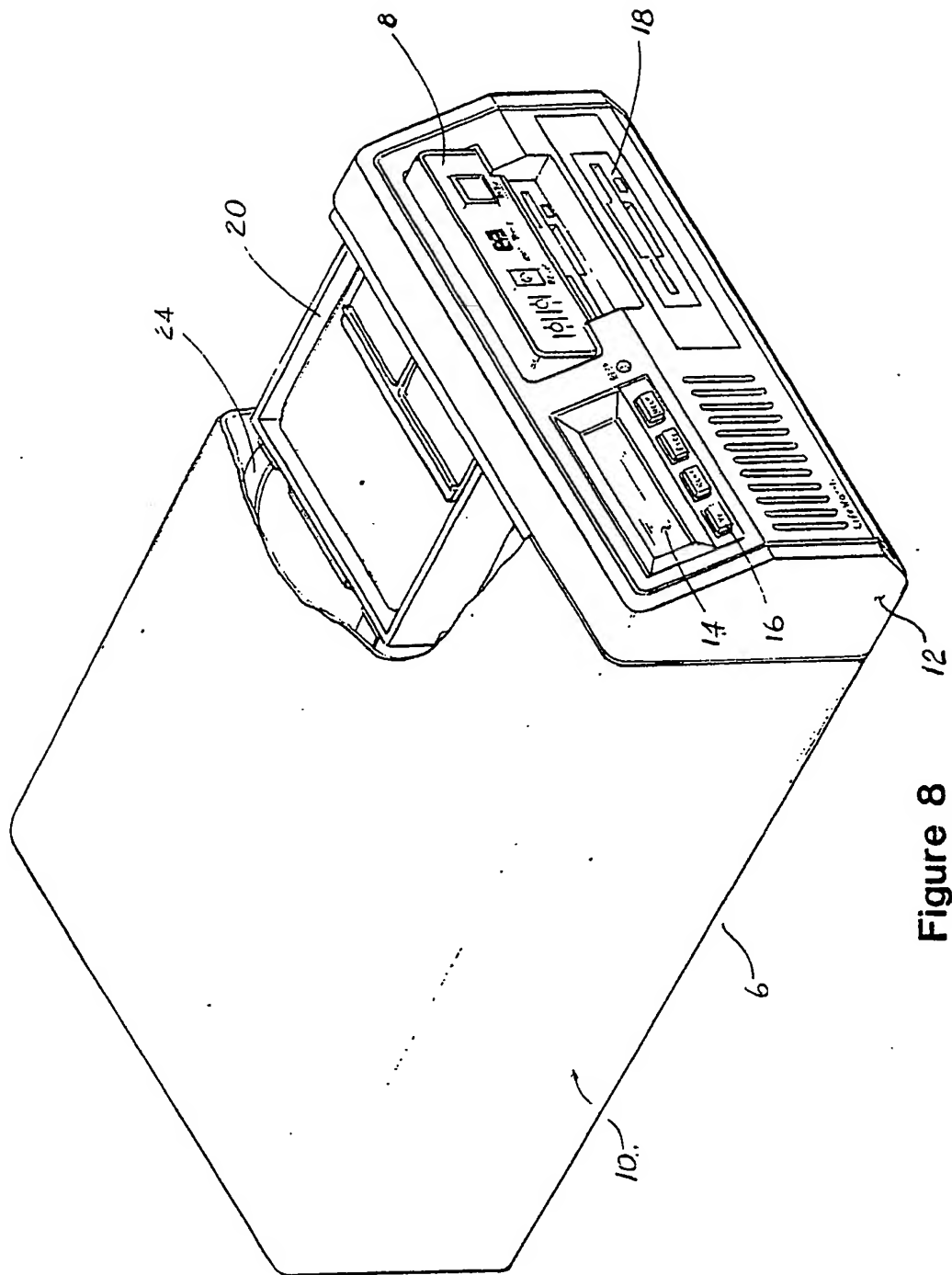


Figure 8

INTERNATIONAL SEARCH REPORT

International Application No **PCT/US86/00719**

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ³

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (4): A61B 5/08

U.S. Cl. 128/716

II. FIELDS SEARCHED

Minimum Documentation Searched ⁴

Classification System

Classification Symbols

| | |
|------|----------------------------------|
| U.S. | 128/670, 721, 722, 723, 773, 716 |
|------|----------------------------------|

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched ⁵

III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴

| Category ⁶ | Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷ | Relevant to Claim No. ¹⁸ |
|-----------------------|--|-------------------------------------|
| Y | US, A, 4,506,678 (RUSSELL et al) 26 March 1985, see the entire document. | 1-31 |
| A | US, A, 4,494,553 (SCIARRA et al) 22 January 1985, see the entire document. | 1-31 |
| A | US, A, 4,495,537 (PROSS et al) 22 May 1984, see the entire document. | 1-31 |
| A | US, A, 4,365,636 (BARKER) 28 December 1982, see the entire document. | 1-31 |
| Y | US, A, 4,307,728 (WALTON) 29 December 1981, see the entire document. | 1-31 |
| A | US, A, 4,146,385 (LAWSON) 27 March 1979, see the entire document. | 1-31 |
| Y | US, A, 4,356,825 (VETH) 02 November 1982, see the entire document. | 1-31 |

* Special categories of cited documents: ¹⁵

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the International filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the International filing date but later than the priority date claimed

"T" later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search ¹

11 June 1986

Date of Mailing of this International Search Report ²

20 JUN 1986

International Searching Authority ¹

ISA/US

Signature of Authorized Officer ¹⁰

E. Coven